UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

PATRICIA A. KING,	)	**CIVIL ACTION NO: 11-cv-00127-RWT**
	)	
Plaintiff,	)	
	)	**JUDGE:**
V.	)	
	)	
PFIZER PHARMACEUTICAL COMPANY, INC.,	)	**MAGISTRATE:**
	)	
	)	
Defendant.	)	

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

Defendant Pfizer Inc ("Pfizer") respectfully submits this memorandum of law in support of its motion, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss Plaintiff's complaint with prejudice for failure to state a claim upon which relief can be granted.

PRELIMINARY STATEMENT

In this *pro se* products liability action, Plaintiff Patricia King alleges she sustained personal injuries by ingesting Lipitor, a prescription medication manufactured by Pfizer and approved by the FDA to treat high cholesterol. Specifically, Plaintiff alleges that her primary physician prescribed Lipitor to her in 2007 and that, in 2009, she "began to experience increasing pain and numbness in her legs and weakness in both her arms and legs," which "became increasingly severe and spread throughout her entire right and left legs." (Compl. at 2:3, 2:8-11.) Plaintiff alleges that she "researched the side effects of the . . . medications she was taking" and determined that "[o]nly Lipitor . . . has as a side effect, known to [Pfizer], the kind of muscle pain and weakness Plaintiff was experiencing." (*Id.* at 2:23-3:2.)

However, the potential side effect of muscle pain and weakness is, and at all relevant times has been, included within the warnings section of the FDA-approved label for Lipitor. All

versions of the Lipitor label in effect in 2007 specifically stated in the "Warning" section that Lipitor can cause "muscle aches or muscle weakness," and that "[p]atients should be advised to *report promptly unexplained muscle pain, tenderness or weakness*, particularly if accompanied by malaise or fever." (*See* Ex. A, 2007 Lipitor Labels, Warnings (emphasis added).) And the current Lipitor label, effective since June 2009, contains nearly identical statements under "Warnings and Precautions." (*See* Ex. B, 2009 Lipitor Label, Warnings and Precautions.)

The only purported legal theory Plaintiff sets forth in her Complaint is that "[s]ince [Pfizer] put into the marketplace a drug, which even if taken as prescribed will cause serious and potentially life-threatening damage to some patients, [Pfizer] must compensate those patients who suffer serious adverse consequences from taking [Pfizer's] product." (Compl. at 3:6-10.) This fails to state a viable claim for two independent reasons:

First, Plaintiff's Complaint fails to state a claim because it does not allege facts plausibly supporting the elements of any cognizable cause of action. Maryland law provides that to assert a products liability claim against a manufacturer of prescription medications, the plaintiff must allege that the manufacturer failed to warn her physician of the harm allegedly suffered by the plaintiff. Plaintiff does not allege any facts plausibly showing a failure to warn, let alone supporting any other theory of defect. Instead, she alleges only that Pfizer "must compensate those patients who suffer serious adverse consequences from taking [Lipitor]," a basis for liability not recognized under Maryland law. As such, she has failed to state a plausible claim.

Second, Plaintiff cannot plead a plausible failure-to-warn claim because her allegations show that Pfizer's warning for Lipitor was adequate as a matter of law. Plaintiff claims an injury of "muscle pain and weakness" due to Lipitor, but the Lipitor label *specifically warned*, at all relevant times, of the potential for "muscle pain . . . or weakness." Courts in this district have

repeatedly recognized that product liability claims regarding prescription medicines fail as a matter of law where, as here, the FDA-approved label warns of the risk which allegedly caused the plaintiff's injury. Because the Lipitor label does just that, Plaintiff's Complaint fails as a matter of law.

Accordingly, the Court should dismiss Plaintiff's Complaint with prejudice.

STANDARD FOR DISMISSAL

The Supreme Court has established a two-step analysis for evaluating the sufficiency of a complaint pursuant to a Rule 12(b)(6) motion to dismiss. First, the district court should identify any conclusory allegations in the complaint, because the court is "not bound to accept as true a legal conclusion couched as a factual assertion." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quotation omitted); *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). Next, the district court should assume the truth only of the remaining "well-pleaded factual allegations" to determine whether the complaint pleads "a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. To be facially plausible, a complaint must "plead[] factual content that allows the court to draw the *reasonable inference* that the defendant is liable for the misconduct alleged," which requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949 (emphasis added). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quotation omitted). Finally, "[a]lthough this Court accords *pro se* complaints liberal construction, it cannot ignore a clear failure to allege facts that set forth [cognizable] claims." *Hodge v. Bd. of County Comm'rs*, No. 10-2396, 2010 WL 4068793, at *1 (D. Md. Oct. 15, 2010) (Titus, J.).

ARGUMENT

I. PLAINTIFF FAILS TO STATE A PLAUSIBLE CLAIM FOR RELIEF

Plaintiff's Complaint must be dismissed because she fails to allege facts plausibly supporting the elements of any product liability cause of action cognizable under Maryland law. Initially, Plaintiff does not even identify any cause of action upon which she bases her assertion, other than her broad and incorrect claim that manufacturers must compensate persons injured by their products. Moreover, Plaintiff does not allege any facts that can be fairly read to support a product liability cause of action under Maryland law.

For product liability cases under Maryland law, "the critical inquiry is whether a product is defective." *Simpson v. Standard Container Co.*, 72 Md. App. 199, 203 (1987); *see also Phipps v. General Motors Corp.*, 278 Md. 337, 344 (1976). Typically, a product may be defective under three theories: design defect, manufacturing defect, or failure to warn. *See Simpson*, 72 Md. App. at 203. However, this Court has recognized that, for product liability claims under Maryland law with respect to prescription medications, only failure-to-warn claims are cognizable. *See Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (holding prescription medications are not defective "unless the manufacturer has failed to provide adequate warnings of the drug's possible dangers."); *see also Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573-74 (D. Md. 2006) ("Prescription drugs are defective only if the risks are inadequately disclosed."). [1] This is so because prescription medications are generally recognized as "unavoidably unsafe" products and, therefore, are not defective if they are

[1] To the extent that Maryland law may recognize a claim of manufacturing defect with respect to prescription medications, Plaintiff has not alleged it here. Indeed, she claims that her harm stems from a characteristic that is common to *all* Lipitor, not a characteristic unique to the Lipitor she consumed.

accompanied by adequate warnings given to the plaintiff's prescribing physician. *See Fellows*, 502 F. Supp. at 300 (citing Restatement (Second) of Torts § 402A cmt. k).

Accordingly, Plaintiff may state a claim against Pfizer with respect to Lipitor only by alleging that Pfizer failed to adequately warn her prescribing physician of the injury she allegedly suffered due to Lipitor. *See Ames*, 431 F. Supp. 2d at 572 ("Maryland law recognizes the 'learned intermediary' doctrine, which provides that manufacturers need only warn the prescribing physician and not the patient directly."). Yet, Plaintiff makes no such allegations. Indeed, Plaintiff does not allege *any* defect with respect to Lipitor, let alone a failure to warn. Rather, she claims only that Pfizer is liable to her simply because it manufactured a medication that could cause harm and allegedly did cause her harm. (*See* Compl. at 3:6-10.) These allegations do not support a claim for relief under Maryland law. Accordingly, Plaintiff's Complaint should be dismissed.

II. PLAINTIFF'S CLAIMS ARE BARRED BECAUSE THE LIPITOR LABEL WAS ADEQUATE AS A MATTER OF LAW

In addition to failing to plead facts supporting the elements of a cause of action, the facts Plaintiff's Complaint does plead – together with the attached judicially noticeable FDA-approved Lipitor labels – affirmatively show that the Lipitor labels gave warnings as to the injuries alleged and were, therefore, adequate as a matter of law. As established above, Maryland law provides that only failure-to-warn claims are cognizable with respect to prescription medications. Moreover, in the case of such medications, a manufacturer's duty to warn flows to the prescribing physician, not to the patient-plaintiff. *See Ames*, 431 F. Supp. 2d at 572. Thus, if a manufacturer provides adequate warnings regarding a prescription-only medication to the prescribing physician, the plaintiff's claims fail as a matter of law. *Id.*; *see also Lee v. Baxter Healthcare Corp.*, 898 F.2d 146, 1990 WL 27325, at *5 (4th Cir. 1990) (table

decision) (applying Maryland law). A warning is adequate as a matter of law "if it explains the risk which allegedly caused the plaintiff's injury." *Lee*, 1990 WL 27325, at *5 (citing *Weinberger v. Bristol-Meyers Co.*, 652 F. Supp. 187, 190 (D. Md. 1986)).

Here, Plaintiff's Complaint fails as a matter of law because Pfizer gave adequate warnings regarding Lipitor to Plaintiff's physician. Plaintiff seeks compensation from Pfizer for "muscle pain and weakness" allegedly caused by Pfizer. Yet, this very injury is clearly warned of in the FDA-approved warning labels for Lipitor that were in effect from the time Plaintiff was first prescribed Lipitor in 2007 up to when she allegedly sustained injuries from Lipitor in 2009. Each of those labels, which are subject to judicial notice by this Court,[2] includes a specific warning that Lipitor can cause "muscle aches or muscle weakness" and directs that "[p]atients should be advised to *report promptly unexplained muscle pain, tenderness, or weakness*, particularly if accompanied by malaise or fever." (*See* Ex. A, 2007 Lipitor Labels, Warnings (emphasis added); Ex. B, 2009 Lipitor Label, Warnings and Precautions (emphasis added).) The language used in these labels is nearly identical; indeed, the only notable differences these labels are matters of formatting. Moreover, the 2009 Lipitor label again advises, under "Patient Counseling Information," that "[a]ll patients starting therapy with LIPITOR should be advised of the risk of myopathy and told to *report promptly any unexplained muscle pain, tenderness, or weakness*." (Ex. B, 2009 Lipitor Label, Patient Counseling Information (emphasis added).)

[2] The content of an FDA-approved label for a prescription medication, which is readily available on the FDA website, is a proper subject of judicial notice on this motion to dismiss because it is a fact "not subject to reasonable dispute [and] 'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'" *In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (quoting Fed. R. Evid. 201) (granting motion to dismiss based in part on content of FDA label for medications at issue).

Thus, the Lipitor label is adequate as a matter of law because it "explains the risk which allegedly caused the plaintiff's injury." *See Lee*, 1990 WL 27325, at *5. Courts applying Maryland law have consistently held that FDA warning labels were adequate as a matter of law where, as here, the label directly warned of the injury alleged by the Plaintiff. *See Weinberger*, 652 F. Supp. at 190 (holding that warning was adequate as a matter of law where it "clearly alerted" prescribing physician to risk of injury sustained by plaintiff); *Ames*, 431 F. Supp. 2d at 573 (holding that warning was adequate as a matter of law where it listed plaintiff's symptoms in "Warnings" section and noted plaintiff's alleged diseases in "Adverse Reactions"); *see also Lee*, 1990 WL 27325, at *5 (holding that label adequately warned of risk of post-implantation rupture of breast implant by stating that it recommended replacement in the case of rupture).

The Lipitor label, thus, is adequate on its face, and Plaintiff's claims fail as a matter of law. Indeed, Plaintiff has not alleged any factual basis from which the Court could plausibly infer that the Lipitor warning regarding "muscle pain . . . or weakness" was inadequate to warn Plaintiff of the risk of the "muscle pain and weakness" she alleges she sustained. *Cf. Bailey v. Janssen Pharm., Inc.*, 288 F. App'x 597, 609 (11th Cir. 2008) (affirming dismissal of failure-to-warn complaint where plaintiff did not "recite the contents of the warning label or the information available to [plaintiff's] physician or otherwise describe the manner in which the warning was inadequate"). Accordingly, because Plaintiff's physician was warned of the specific injury alleged, Plaintiff's Complaint fails as a matter of law under Maryland law and should be dismissed with prejudice.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Court enter judgment dismissing Plaintiff's complaint with prejudice in its entirety.

Dated: January 17, 2011

Respectfully submitted,

_____/s/_____
Richard M. Barnes (Bar No. 00669)
Derek M. Stikeleather (Bar No. 27815)
Goodell, DeVries, Leech & Dann, LLP
One South Street – 19th Floor
Baltimore, MD 21202
(410) 783-4000
(410) 783-4040 (fax)

rmb@gdldlaw.com
dstikeleather@gdldlaw.com

Attorneys for Defendant Pfizer Inc

CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2011, I filed the foregoing motion, memorandum, and proposed order with the Clerk of the Court and served a copy of the foregoing upon the following by U.S. First Class Mail, postage pre-paid:

Patricia A. King
5900 Forest Road
Cheverly, Maryland 20785-2946

/s/
Derek M. Stikeleather

Attorneys for Defendant Pfizer Inc